(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (d) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (c) of this section.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, selenium-75, or carbon-14; 50 microcuries of hydrogen-3 (tritium); or 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, ''Caution, Radioactive Material'', and ''Not for Internal or External Use in Humans or Animals.''

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package: [1]

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.2001.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.